

# Food Defense

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# Overview

- General approaches to Food Defense since 9/11
- Issues to consider as we continue to move forward



# Food Defense

## Major areas of focus in FDA

- Vulnerability and Threat Assessments
- Industry Guidance and Preventive Measures
- Imports – Strengthen Controls
- Research
- Emergency Preparedness and Response
- Bioterrorism Act Regulations



# Vulnerability and Threat Assessments

- Vulnerability Assessments
  - Battelle Study (Prior to 9/11)
  - FDA-CFSAN Assessment
    - Operational Risk Management
  - IFT Task Order
    - Operational Risk Management
  - CARVER Analysis
    - Internal and with industry



# Industry Guidance and Preventive Measures

- Guidance to Industry
  - Processors
  - Importers
  - Retail
  - Cosmetics
  - Milk

<http://www.cfsan.fda.gov/~dms/guidance.htm>

- Developing Shields



# Strengthen Imports

- New Hires
- New Ports
- Prior Notice Center
- Mobile laboratories



# Research Agenda

## New Methods

Development of rapid, reliable methods to detect, enumerate and identify potential agents in foods

## Prevention Technologies

Technologies to improve safety of foods

Provide “shields” in the event of contamination of foods

## Agent Characteristics

Ability of threat agents to survive and grow in foods, and means to inactivate

## Dose Response/Threat Assessments

Ability of foodborne threat agents to cause mass casualties



# Emergency Preparedness and Response

- Emergency Plans
- Emergency Exercises
- Lab Capacity/Surge Capacity





# Bioterrorism Act 2002

- Directed FDA to take aggressive steps to protect the public health from deliberate and accidental contamination of our food supply.
  - Recordkeeping
    - Published final rule December 9<sup>th</sup>. 2004
  - Administrative Detention
    - Published final rule May 27<sup>th</sup>. 2004
  - Registration
    - Interim final rule Registration System operational Oct. 16, 2003
  - Prior Notice
    - Interim final rule Prior Notice Systems operational Dec. 12, 2003



As we move forward



# Spectrum of issues

- Continuum of being prepared
  - Prevention
  - Preparedness
  - Response
  - Recovery
- Multiple factors to consider
  - Stakeholders
  - Foods
  - Agents
  - Scenarios



# Spectrum of Stakeholders

- Federal
- State
- Tribes
- Local
- Industry



# Spectrum of foods

- Infant formula
- Baby food
- Milk
- Yogurt
- Ice cream
- Soft drinks
- Fruit juice
- Breaded food
- Cereal
- High fructose corn syrup (ingredient)
- Gum arabic (ingredient)
- Produce
- Honey
- Peanut butter
- Seafood, cooked
- Deli salad
- Entrées, cooked
- Water, bottled
- Canned food, low-acid
- Spices
- Dietary supplements
- Vitamins
- Flour



# Spectrum of Agents

- Grouping of agents with similar characteristics:
  - Spore-forming bacteria
  - Heat-labile toxins
  - Heat-stable toxins
  - Vegetative bacteria
- Chemicals
  - water/lipid solubility
  - high/low dose
  - heat stability
  - odor/flavor/color



# Spectrum of Scenarios that may be our first indication of a deliberate contamination

- Sick animals
- Sick humans
- Credible threats
- Surveillance systems



# Response

- How to ensure a seamless and integrated response to various scenarios?
- Harmonized role of stakeholders
  - Local authorities
  - States (Agriculture and Public Health)
  - Federal
  - Industry
- LRN and FERN laboratories





# Multiple and overlapping laboratory needs

- Diagnosis in the case of human or animal illness
- Testing of a food commodity
  - Which food
  - Which agent
  - Level of contamination
- Containment
  - Extent of contamination
- Recovery



# Goals for reacting

- Ability to undertake testing for specific select agents in both a clinical sample and food matrix setting,
- Demonstrated ability to be able to respond to either an “unknown” or surge for the testing of both clinical and food matrix samples,
- A strategy to ensure that the agriculture and public health safety components within a state have a means of rapid communication with each other and their federal counterparts,
- A “low threshold” for keeping each other informed,
- A controlled response using the best scientific information



# Summary

- FDA is working on multiple fronts for Food Defense
- Continue to foster preparedness and good communication between stakeholders
- It is critical that the response network be ready to perform and be integrated to provide a seamless approach to dealing with a terrorist event involving the food supply.
- Working closely with stakeholders is the key to being prepared



# Questions?

